

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents  
Washington, D.C. 20231

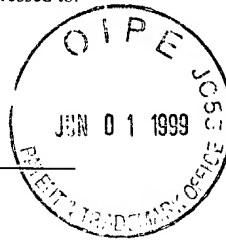
On

5/28/99

TOWNSEND and TOWNSEND and CREW LLP

By:

*John Kane*



PATENT  
Attorney Docket No.: 23070-689-3  
Client Reference No.: 96-185-4

#15  
CHK  
6-1-99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GRAY et al.

Application No.: 08/892,695

Filed: July 15, 1997

For: GENES FROM THE 20Q13  
AMPLICON AND THEIR USES

Examiner: Unger, S.

Art Unit: 1642

RESPONSE TO RESTRICTION  
REQUIREMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The following is offered in response to the Office Action mailed February 1, 1999. The restriction requirement of the Office Action mailed November 18, 1998 has been withdrawn and replaced by those of the present Office Action, which is the *third* restriction requirement issued in the present case.

In the present restriction, applicants again elect with traverse to prosecute the claims of Group II (claims 26-41), directed to methods of screening for neoplastic cells and detecting mutations using nucleic acid probes of the invention. In addition, the Examiner now alleges that claims 1, 26, 42, and 44 recite improper Markush groups and requires that an additional election be made among the sequences recited in these claims. Applicants hereby elect with traverse to prosecute claims directed to SEQ ID NO: 9 and SEQ ID NO: 10. As

pointed out in the previous response, SEQ ID NO:9 and SEQ ID NO: 10 comprise the same coding sequence.

Applicants particularly traverse the rejection based on an alleged improper Markush grouping. The allegation of improper Markush is based on an allegation that the sequences are "biologically and chemically distinct, unrelated in structure and function, made by and used in different methods" (*see*, Item 3 of the Office Action). The Examiner also alleges that applicants have shown "no particular physiological correlation" between the molecules (*see, e.g.* Item 5). The Office Action provides no explanation as to how these conclusory statements relate to the determination of whether a single invention is claimed. As explained below, the case law and the MPEP are very explicit with regard to the proper analysis required in the present case. Application of the proper law requires a conclusion that, at most, a species election is required.

MPEP §803.02, which deals with restriction of claims comprising Markush groups, states that "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions." Applicants note that MPEP §803.04 explicitly addresses applications with more than one nucleotide sequence. That section states:

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.

Thus, in light of the clear directions in the MPEP, it is respectfully submitted that at least 10 of the 12 sequences *must* be examined. Applicants respectfully request that some explanation be provided to show why §803.04 should not be applied to the present case.

Even assuming the Examiner does not apply §803.04, the Examiner has failed to provide sufficient reasoning or evidence to show that the present claims constitute an improper Markush. The restriction of Markush claims is dealt with in MPEP §803.02. There, it is noted that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 206

①

USPQ 300 (CCPA1980). That section also sets forth the test for determining whether unity of invention exists in a Markush claim. It is as follows:

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

The Office Action lacks any discussion of the claimed nucleic acids in light of the requirements set forth in §803.02. Indeed, the species recited in the claims meet both requirements. As set forth throughout the specification, the nucleic acids were all identified in a single amplicon at chromosome 20q13. As fully explained in the specification, amplification in this region is associated with cancer. Thus, all the nucleic acids share a common utility in that they can be used to detect the presence of the 20q13 amplicon. The nucleic acid molecules also share a substantial structural feature because they are all composed of purine and pyrimidine bases. This shared structural feature is essential to their ability to hybridize to nucleic acid molecules and thereby act as probes.

Nothing in the Office Action addresses these issues. Instead the Examiner merely offers conclusory statements regarding the claimed nucleic acids "structure and function". In the absence of some reasoning or evidence that the claimed nucleic acids lack unity of invention using the analysis required in MPEP §803.02, the assertion of improper Markush should be withdrawn.


As noted above, §803.02 addresses restriction requirements for Markush claims. The third paragraph of this section explicitly states Markush claims "can include independent and distinct inventions." This is true even where two or more of the members are "so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)." In applications containing such claims (which presumably also lack unity of invention), the MPEP requires the examiner to impose "a provisional election of a *single species* prior to examination on the merits" (emphasis added). Thus, in cases in which a Markush group includes distinct inventions, the MPEP requires *election of species* not restriction as set forth in the present Office Action. Nothing in the Office Action provides any reasoning to show why a

species election would not be appropriate, particularly in light of the clear directions from the MPEP.

Finally, applicants note that this is the third restriction issued in the present case. The previous action provided a reasonable means to allow the Examiner to restrict search to individual nucleic acids without burdening the applicant with the expense of filing *twelve* different applications to pursue claims to each of the claimed nucleic acids. Applicants respectfully submit that the equities of the situation, not to mention compact and efficient prosecution, require that, at a minimum, the species election of the previous action be reinstated.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 576-0200.

Respectfully submitted,

  
Kevin Bastian  
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: (415) 576-0200  
Fax: (415) 576-0300  
KLB